

### **Remarks/Arguments**

Applicants have received and carefully reviewed the Office Action of the Examiner mailed June 25, 2008. Currently, claims 1-47, 54, and 55 remain pending. Claims 1-47, 54, and 55 have been rejected. Favorable consideration of the following remarks is respectfully requested.

### **Claim Rejections – 35 USC § 102**

Claims 1, 2, 7, 14-32, and 34-47 were rejected under 35 U.S.C. 102(b) as anticipated by Ehnholm et al. (U.S. Patent No. 6,975,896), hereinafter Ehnholm. After careful review, Applicant must respectfully traverse this rejection.

*“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.”* Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). (See MPEP § 2131). Nowhere does Ehnholm appear to teach or suggest, “wherein the second MRI process is adapted to detect the selected MRI detectable nuclei contained in the medical device imaging material and the selected MRI detectable nuclei is not the same nuclei that the first MRI process is adapted to detect”, as recited in claim 1. Ehnholm explicitly uses a first imaging process including external fiducials (50) and subject data and a second imaging process including device associated fiducials (50), said fiducials being described as having common structure at col. 4, lines 20-34 as “the fiducials **50** have non-ferromagnetic shells **54** which define a spherical cavity filled with a liquid or gel compound that includes a Fl<sup>19</sup> fluorine isotope.” (Note that Ehnholm does not use the standard notation, <sup>19</sup>F, for the fluorine isotope in question. To avoid possible confusion, when discussing the Ehnholm reference, the Fl<sup>19</sup> symbol will be included.) The fiducials affixed to the patient are imaged with, and then separated from the subject proton spectra, and stored in a subject data memory in the first imaging process. The images of the subject are then combined to produce a single image which shows the fiducials relative to selected portions of the body. It is at this point, prior to the introduction of the surgical instrument or accessory, that the fiducial data is reconstructed and stored in a fiducial image memory (64) referenced by the Examiner. It is unclear why patient fiducials attached to the patient and imaged with the patient in a first MRI process,

which occurs prior to the introduction of the medical device, would be characterized by the Examiner as “considered to be part of the surgical tool”. The medical device or “surgical accessory is also instrumented with fiducials”, and is introduced into the patient, whereupon second “additional imaging procedures are conducted” which clearly differentiates the first external fiducials cited by the Examiner (column 5, lines 9-17) and the second internal fiducials associated with the instrument (column 5, lines 17-44) as well as the first and second MRI imaging processes.

Subsequently, in the method of Ehnholm, an instrument associated phantom image is said to be generated by device image generator (68) and inserted within the reconstructed images stored in the fiducial image memory (64). The fiducials in question appear to be identical in composition although they may differ in size. Accordingly, Ehnholm appears to disclose a method in which the first and second images both include a selectable MRI detectable nuclei which is the same nuclei, namely a  $^{19}\text{F}$  fluorine isotope, that the first MRI process and the second MRI process are adapted to detect. It appears that the fiducials within two separate  $^{19}\text{F}$  images are used to align two images produced by two imaging processes in the method of Ehnholm. In contrast, the method of the present invention does not require external fiducials to achieve registration between the images of the subject, with attached fiducials, and the succession of medical device fiducial images to place the medical device in registration relative to the images of the subject.

In a separate embodiment, also cited by the Examiner and described at column 6, lines 12-27 and Fig. 3, Ehnholm appears to describe an embodiment in which a local MRI receive coil probe, including the above discussed associated probe fiducials, is used in conjunction with the external fiducials and the subject image to locate the probe in reference to the subject within the combined images. This embodiment also appears to require that the first and second images both include a selectable MRI detectable nuclei which is the same nuclei, namely the  $^{19}\text{F}$  fluorine isotope.

Ehnholm must teach each and every element in as complete detail as is contained in claim 1, as is required for anticipation, and does not appear to do so in either of the two

embodiments discussed by the Examiner. Applicant, therefore respectfully requests that the rejection of claim 1 be withdrawn.

The Examiner has noted a possible interpretation of claim 1 in which the MRI enhancement of claim 1, line 10 is said to “merely require detection of a signal without making a relationship with the detecting of nuclei”. Although Applicants are comfortable that the portion of the claim in question clearly described a second MRI process in which a receiver coil, associated with the medical device, provides MRI enhancement to the second MRI process said process being adapted to detect the MRI detectable nuclei contained in the medical device in a second image, the claim has been further amended to advance prosecution.

Additionally, for similar reasons, as well as others, claims 2, 7, 14-32, and 34-47, which depend from claim1 and include significant additional limitations, are believed to be not anticipated by Ehnholm and Applicants respectfully request withdrawal of the rejections.

#### **Claim Rejections – 35 USC § 103**

Claims 3-6 and 8-13 were rejected under 35 U.S.C. 103(a) as being unpatentable over Ehnholm in view of Chui (U.S. Published Patent Application No. 2002/0101241). After careful review, Applicant must respectfully traverse this rejection.

“All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). (MPEP § 2143.03). Although the rejection is over Ehnholm in view of Chui, the discussion provided in the Office Action Summary is of an unidentified Pacetti reference which is presumed to be U.S. Patent No. 6,574,497. There appears to be no discussion of either Ehnholm or Chui. In an attempt to be responsive to the Office Action, the following remarks will be directed toward a presumed combination of Ehnholm, Chui, and Pacetti although it is difficult to see what form such a rejection might take in view of the discussion of Ehnholm presented above.

Ehnholm appears to disclose a method in which a first and second images both include a selectable MRI detectable nuclei which is the same nuclei, namely a  $^{19}\text{F}$  fluorine isotope, that the first MRI process and the second MRI process are adapted to detect. Chui presumably was cited to supplement the Ehnholm disclosure of an internal antenna with additional antenna configurations. Pacetti appears to have been provided solely for the purpose of adding phosphor (sic) and iodine nuclei to the list of suitable MRI detectable nuclei which might be used in the method of Ehnholm. Replacing  $^{19}\text{F}$  of Ehnholm by  $^{31}\text{P}$  does not appear to address the fundamental problem which is that both the first MRI process and second MRI process of Ehnholm appear to detect the same MRI detectable nuclei. Iodine appears to be disclosed by Pacetti only in the context of a fluoroscopy contrast agent characterized as follows: "iodinated contrast agents are nephrotoxic with a real incidence of acute renal failure, particularly in patients with compromised renal function. Allergic reactivity also serves as a contraindication for certain patients." and so may be inappropriate in the MRI process of Ehnholm. In any event, the agents of Pacetti and the antennae of Chui do not appear to overcome the deficiencies of Ehnholm and Applicants respectfully request that the rejections of claims 3-6 and 8-13 be withdrawn. Additionally, for similar reasons, as well as others, claims 3-6 and 8-13, which depend from claim 1 and include significant additional limitations, are believed to be patentable over Ehnholm in view of Chui, with or without Pacetti and Applicant respectfully requests withdrawal of the rejections.

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). (MPEP 2143.03)

If the above discussion is not responsive to the § 103 rejection which the Examiner intended to present, he is invited to clarify the rejection in a future non-final rejection.

Claim 33 was rejected under 35 U.S.C. 103(a) as being unpatentable over Ehnholm in view of Young et al. (U.S. Patent No. 5,817,017). After careful review, Applicant must respectfully traverse this rejection.

Young et al. was presented to provide a microporous material comprising a film or

foam acknowledged by the Examiner to be missing from Ehnholm. Young does not appear to overcome the deficiencies of Ehnholm as discussed in detail above. Accordingly, for similar reasons, as well as others, claim 33, which depends from claim 1 and include significant additional limitations, is believed to be patentable over Ehnholm in view of Young et al. and Applicant respectfully requests withdrawal of the rejection.

Claim 54 was rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti in view of Toyota et al. (U.S. Patent No. 4,713,722), hereinafter Toyota. After careful review, Applicant must respectfully traverse this rejection.

Pacetti appears to disclose a single MRI imaging process in which two MRI detectable nuclei are imaged simultaneously in a single image. Because of the difference in resonance frequency, the two MRI detectable nuclei may be identified and displayed in a different intensity, color, or even in separate images. As described in the cited passages, the tagged device and method of Pacetti appear to use a single MRI process to capture a single image. Pacetti does not appear to teach or disclose a second MRI process producing a second image which may be combined with the first image, further wherein the first and second MRI processes utilize the same frequency, but rather use a first magnetic field strength for the first MRI process that is different from a second field strength used for the second MRI process. This difference may be seen clearly at column 7, lines 49-61 wherein a single magnetic field strength of 1.5 Tesla is used to record a single image having components at 63.18 MHz and 60.08 MHz rather than at the single frequency of claim 54. Were one to alter the magnetic field strength of Pacetti as suggested by Toyota, one would impermissibly alter the principle of operation of Pacetti which appears to rely upon separating the frequency related components of a single image for differentiated display rather than capturing two separate images which are later combined. (MPEP 2143.02, VI.) Accordingly, the combination of Pacetti in view of Toyota appears to be inappropriate and Applicant respectfully requests that the rejection be withdrawn.

Claim 55 was rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti in view of Schweighardt et al. (U.S. Patent No. 5,068,098), hereinafter Schweighardt. After

careful review, Applicant must respectfully traverse this rejection.

As noted above, Pacetti appears to capture a single image in a single MRI process and to separate frequency related components associated with two MRI detectable nuclei within a single image for differentiated display rather than capturing two separate images which are later combined. The specification of perfluoro-[15]-crown-5-ether as the source of  $^{19}\text{F}$  to be used as one of two MRI detectable nuclei does not correct the deficiencies of the Pacetti reference and does not supply the missing second MRI process or the second image of claim 55 as those terms are used in the pending application. Accordingly, the combination of Pacetti in view of Schweighardt appears to be inappropriate in that the combination does not appear to teach all the claim limitations, as is required to establish a *prima facie* case of obviousness and Applicant respectfully requests that the rejection be withdrawn.

In view of the foregoing, all pending claims are believed to be in a condition for allowance. Reexamination and reconsideration are respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,  
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By their Attorney,

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